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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,498	07/22/2002	Jeffrey W. Chambers	19478-00005	4855

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DICKE, BILLIG & CZAJA, P.L.L.C.
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/064,498	CHAMBERS, JEFFREY W.	
	Examiner	Art Unit	
	Cris L. Rodriguez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 25-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 25-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/3/02, 7/22/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. Figure 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because the figures and references numerals are very small and it is difficult to distinguish the elements in the figures. The references numerals do not comply with 37 CFR 1.84.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

3. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

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4. In response to this requirement, please provide a copy of the following art referred to in the specification on page 5, paragraph [0018], and page 10, paragraph [0033].

5. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 16, 17, 26, 28, 29, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 16 and 32, it seems that something is missing from the claims because the body of the claims start with "said catheter", and it is not clear if applicant is referring to the claimed catheter.
- Claims 26, 28, and 29 are indefinite because it is not clear how the step of advancing can be performed if the guidewire was previously removed in claim 25.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 32-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoste (US 6,508,806).

Hoste discloses a guiding catheter having a body with a proximal section at 12, an intermediated section at 13, and a distal section at the curved tip, and a braid.

10. Claims 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al (US 6,159,187).

Park discloses a guiding catheter having all the elements as claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste.

Hoste discloses the invention substantially as claimed except for the outer diameter set forth in the claim. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hoste with the claimed outer diameter since such modification would have been an obvious design choice. See *In re*

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Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984) where the Federal Circuit held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and the device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

13. Claims 1-10, 14, 15, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Chludzinski et al (US 6,837,890).

Park discloses the invention substantially as claimed (See column 11 for the spacer and the two braided layers). It also set forth that the curved section could have any desirable shape. However, Park fails to specifically disclose the curved shape defining a curvature of ninety degrees or greater.

Chludzinski discloses a catheter having a pre-formed curved section having a curvature of at least ninety degrees in order to steer effectively within the curves of the blood vessel. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Park by providing it with Chludzinski's curved tip section, since Chludzinski suggests that would enhance the steerability of the catheter with the body.

14. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Chludzinski et al, and further in view of Samson et al (US 6,143,013).

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Park/Chludzinski discloses the invention substantially as claimed except for the distal tip being formed of nylon, polyurethane, or plastic.

Samson teaches in columns 10-11 that the outer layer (that could later form the tip in figures 7-10, and 13-14) can be made of nylon, polyurethane, or plastic. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Park/Chludzinski's distal tip by providing it with Samson's materials, since Samson suggests that such would enhance the capabilities of the device.

15. Claims 16, 17, 25, 26, 28, 30, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiemeneij (US 6,620,150) in view of Jafari et al (US 6,652,472).

Kiemeneij discloses a guiding catheter, a guidewire, and a method for steering a guidewire having the steps set forth in the claims (cols. 1-2, and figures 1-6). However, Kiemeneij fails to disclose the guidewire having a variable stiffness, and the step of advancing further the guidewire and catheter.

Jafari teaches that it is well known to use a variable stiffness guidewire in pre-formed guiding catheters (Col. 1, and fig. 1) to improve the steerability of the catheter with the guidewires flexibility. In col. 1, lines 32-36, it teaches the step of further advancing the guidewire and the catheter for additional procedure. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kiemeneij's guidewire by substituting it with the one shown in Jafari in order to improve the steerability of the guiding catheter within the

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body, and further include the step of further advancing the guidewire and the catheter in order to perform an additional procedure.

16. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kiemeneij in view of Jafari, and further in view of Chaisson et al (US 6,086,548).

Kiemeneij/Jafari discloses the invention substantially as claimed. However, Kiemeneij/Jafari fails to disclose the step of administering a medication through the catheter.

Chaisson teaches that it is well known to introduce medicament through the catheter (col. 4 lines 65-67). Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kiemeneij/Jafari's method steps by including the step of administering a medication through the guiding catheter, since Chaisson teaches that it is old and well known to further treat a target site.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 Form.

Allowable Subject Matter

18. Claim 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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19. This Office action has an attached requirement for information under 37 CFR


1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is 571-272-4964. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 16, 2005


Cris L. Rodriguez
Primary Examiner
Art Unit 3763